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Substitute for form 1449A/PTO		Complete If Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	10/719,734
(use as many sheets as necessary)		Filing Date	November 21, 2003
		First Named Inventor	Solomon S. Steiner
		Group Art Unit	1616
		Examiner Name	Alstrum Acevedo, James Henry
Sheet	1	of	1
		Attorney Docket Number	PDT 120/121 DIV CON

**OTHER ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner's Signature	/James Alstrum Acevedo/	Date Considered	12/12/2007
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<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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Sheet 1 of 14

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
/J.H.A.A./	3,906,950	Cocozza		09-23-1975		
	3,921,637	Bennie, et al.		11-25-1975		
	4,153,689	Hirai		05-08-1979		
	4,196,196	Tiholiz		04-01-1980		
	4,211,769	Okada		07-08-1980		
	4,272,398	Jaffe		06-09-1981		
	4,294,829	Suzuki		10-13-1981		
	4,659,696	Hirai		04-21-19		
	4,861,627	Mathiowitz		08-29-1989		
	4,866,051	Hunt		09-1989		
	4,946,828	Markussen		08-07-1990		
	5,006,343	Benson		04-09-1991		
/J.H.A.A./	5,042,975	Chien		08-27-1991		

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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
/J.H.A.A./	EP	0/069/715		Draco AB	01-12-1983		
/J.H.A.A./	EP	0/122/036		Teijin Ltd	10-17-1984		
/J.H.A.A./	EP	0/237/507		Draco AB	09-16-1987		
/J.H.A.A./	EP	0 257 915		Innovata Biomed Ltd.	02-03-1988		
/J.H.A.A./	EP	0/360/340		Akzo	03-28-1990		
/J.H.A.A./	EP	0/364/235		Toyo Jozo Kabushiki	04-18-1990		

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/J.H.A.A./	EP	0606486	Teijin Ltd.	12-23-1993	
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		Number	Kind Code <sup>2</sup> (if known)		
/J.H.A.A./	5,145,684	Liversidge, et al.		09-08-1992	
	5,188,837	Domb		02-1993	
	5,204,108	Illum		04-20-1993	
	5,260,306	Boardman, et al.		11-09-1993	
	5,354,562	Platz		10-11-1994	
	5,364,838	Rubsamen		11-15-1994	
	5,458,135	Patton, et al.		10-17-1995	
	5,482,927	Maniar		01-09-1996	
	5,484,606	Dhabar, et al.		01-16-1996	
	5,492,112	Mecikalski, et al.		02-20-1996	
	5,514,646	Chance, et al.		05-07-1996	
	5,562,909	Allcock, et al.		10-08-1996	
/J.H.A.A./	5,577,497	Mecikalski, et al.		11-26-1996	

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		Office <sup>3</sup>	Number <sup>4</sup>		
No translat	0655237			Hoechst AG	03-26-1996
/J.H.A.A./	EP 0748213			Inhale Therapeutic Sys	12-18-1996
/J.H.A.A./	EP 1/114/644			Genetech, Inc.	07-11-2001
	EP 96911738			Nektar Therapeutics	06-16-2004

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## Substitute for form 1449A/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	3	of	14	Attorney Docket Number	PDT 120/121 DIV CON
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/J.H.A.A./	GB	2,240,337	National Research Development Corp.	07-31-1991		
/J.H.A.A./	JP	0149545	Taisho Pharmaceutical Co.	02-12-1992		

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		Number	Kind Code <sup>2</sup> (if known)			
/J.H.A.A./	5,653,961			McNally, et al.	08-05-1997	
	5,658,878			Bäckström, et al.	08-19-1997	
	5,693,338			Milstein	12-02-1997	
	5,740,794			Smith, et al.	04-21-1998	
	5,747,445			Bäckström, et al.	05-05-1998	
	5,763,396			Weiner, et al.	06-09-1998	
	5,785,989			Stanley, et al.	07-28-1998	
	5,785,049			Smith, et al.	07-28-1998	
	5,807,315			Van Antwerp, et al.	09-1998	
	5,849,322			Ebert, et al.	12-15-1998	
	5,874,064			Edwards, et al.	02-23-1999	
	5,877,174			Ono, et al.	03-02-1999	
/J.H.A.A./	5,901,703			Ohki, et al.	05-11-1999	

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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	JP	363020301A			Dainichi Color and Chem	01-1998		
	PCT	0 220 958 A2			Eli Lilly and Company	05-06-1987		

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/719,734
Sheet	4	of	14	Filing Date	November 21, 2003
				First Named Inventor	Solomon S. Steiner
				Group Art Unit	1616
				Examiner Name	Alstrum Acevedo, James Henry
				Attorney Docket Number	PDT 120/121 DIV CON

/J.H.A.A./	PCT	WO 90/13285	Enzytech, Inc	11-15-1990		
/J.H.A.A./	PCT	WO 91/16882	Lipsome Technology	11-14-1991		
/J.H.A.A./	PCT	WO 91/04011	Riker Laboratories Inc.	04-04-1991		
/J.H.A.A./	PCT	WO 92/08509	MMM	05-29-1992		
/J.H.A.A./	PCT	WO 93/02712	Danbiosyst	02-18-1993		

U.S. PATENT DOCUMENTS						
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		Number	Kind Code <sup>2</sup> (if known)			
/J.H.A.A./	5,912,011			Makino, et al.	06-15-1999	
	5,929,027			Takama, et al.	07-27-1999	
	5,952,008			Bäckström, et al.	09-14-1999	
	5,985,309			Edwards, et al.	11-16-1999	
	5,997,848			Patton, et al.	12-07-1999	
	6,051,256			Platz, et al.	04-18-2000	
	6,063,910			DeBenedetti	05-2000	
	6,099,517			Daugherty	09-08-2000	
	6,153,613			Ono, et al.	11-28-2000	
	6,254,854			Edwards, et al.	07-03-2001	
	6,294,204			Rossling, et al.	09-25-2001	
	6,395,774			Milstein	05-28-2002	
	6,423,344			Platz, et al.	07-23-2002	
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		Office <sup>3</sup>	Number <sup>4</sup>				
/J.H.A.A./	PCT	WO 92/04069		Aktiebolaget astra	03-1992		
/J.H.A.A./	PCT	WO 93/17728		Aktiebolaget Astra	09-1993		
/J.H.A.A./	PCT	WO 93/02712		Danbiosyst UK Limited	02-18-1993		
/J.H.A.A./	PCT	WO 93/18754		Pharmaceutical Discovery	09-30-1993		
/J.H.A.A./	PCT	WO 94/000291		Fisons Plc	01-06-1994		

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/J.H.A.A./	6,436,443			Edwards, et al.	08-20-2002	
	6,440,463			Feldstein, et al.	08-27-2002	
	6,447,753			Edwards, et al.	09-10-2002	
	6,503,480			Edwards, et al.	01-07-2003	
	6,518,239			Kuo, et al.	02-11-2003	
	6,592,904			Platz, et al.	07-15-2003	
	6,635,283			Edwards, et al.	10-21-2003	
	6,676,931			Dugger, III	01-13-2004	
	6,685,967			Patton	02-03-2003	
	6,737,045			Patton	05-18-2004	
	6,949,258			Zhang	09-24-2005	
/J.H.A.A./	7,030,084			Ekwuribe, et al.	04-18-2006	

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/J.H.A.A./	PCT	WO 95/00127		Astra Atkiesbolag	00-1995		
/J.H.A.A./	PCT	WO 95/11666		Coordinated Drug	05-04-1995		
/J.H.A.A./	PCT	WO 95/31979		R.P Scherer International	11-30-1995		
/J.H.A.A./	PCT	WO 95/34294		Hamilton, Brook, Smith, & Reynolds P.C. and Yissum	12-21-1995		
/J.H.A.A./	PCT	WO 97/49386		Peptide Delivery Systems	12-31-1997		

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/J.H.A.A./	RE35,862			Steiner, et al.	07-28-1998	
	RE37,053			Hanes, et al.	02-13-2001	
	2003/0064097			Patel, et al.	04-03-2003	
	2003/0068378			Chen, et al.	04-10-2003	
	2003/0194420			Holl, et al.	10-16-2003	
	2004/0151774			Pauletti, et al.	08-05-2004	
	2004/0247628			Lintz, et al.	12-09-2004	
	2004/157928			Kim Jae-Hwan, et al.	08-12-2004	
	2005/0080000			Thurow Horst, et al.	04-14-2005	
	6,737,045			Patton	05-18-2004	
/J.H.A.A./	6,949,258			Zhang	09-24-2005	

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duplicate	7,030,084	Ekwonue, et al.	04-18-2000
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/J.H.A.A./	PCT	WO 01/00654		Steiner	01-2001		
/J.H.A.A./	PCT	WO 01/07107		PharmaceuticalDiscovery Corporation	02-01-2001		
/J.H.A.A./	PCT	WO 03/057170		Emisphere Technologies	07-17-2003		
/J.H.A.A./	PCT	WO 03/086345		Atrix Laboratories, Inc.	10-23-2003		
/J.H.A.A./	PCT	WO 03/094951		Novo Nordisk As	11-20-2003		
/J.H.A.A./	PCT	WO 04/056314		Nastech Pharmaceutical Company Inc	07-08-2004		

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Substitute for form 1449A/PTO				Complete if Known	
				Application Number	10/719,734
				Filing Date	November 21, 2003
				First Named Inventor	Solomon S. Steiner
				Group Art Unit	1616
				Examiner Name	Alstrum Acevedo, James Henry
Sheet	8	of	14	Attorney Docket Number	PDT 120/121 DIV CON

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
/J.H.A.A./	2005/0153874	Cheatham		07-14-2005		
	2004/0096403	Steiner		05-20-2004		
	2003-0017211	Steiner		01-23-2003		
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	2005/0214251	Steiner		03-11-2005		
	2007/0086952	Steiner		09-26-2006		
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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
/J.H.A.A./	PCT	WO 05/089722			Biodel, Inc	09-29-2005		
/J.H.A.A./	PCT	WO 02/11676			DMI Biosciences, Inc.	02-14-2002		
/J.H.A.A./	PCT	WO 04/075919			Medtronic Minimed, Inc	09-10-2004		

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Sheet	9	of	14
		Attorney Docket Number	PDT 120/121 DIV CON

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
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(use as many sheets as necessary)				Filing Date	November 21, 2003
				First Named Inventor	Solomon S. Steiner
				Group Art Unit	1616
				Examiner Name	Alstrum Acevedo, James Henry
Sheet	10	of	14	Attorney Docket Number	PDT 120/121 DIV CON

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/J.H.A.A./		ENGELGAU, et al., "Screening for type 2 diabetes," <i>Diabetes Care</i> 15(3):1-31 (2000).		
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Application Number	10/719,734
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First Named Inventor	Solomon S. Steiner
Group Art Unit	1616
Examiner Name	Alstrum Acevedo, James Henry
Attorney Docket Number	PDT 120/121 DIV CON

Sheet 11 of 14

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Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
/J.H.A.A./	KOHLER, "Aerosols for Systemic Treatment", <i>Lung Suppl.</i> 677-683 (1990)	T <sup>2</sup>
/J.H.A.A./	KOMADA, et al., "Intratracheal delivery of peptide and protein agents: absorption from solution and dry powder by rat lung," <i>J. Pharm. Sci.</i> 83(6): 863-867 (1994).	
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/719,734
Sheet	12	of	14	Filing Date	November 21, 2003
				First Named Inventor	Solomon S. Steiner
				Group Art Unit	1616
				Examiner Name	Alstrum Acevedo, James Henry
				Attorney Docket Number	PDT 120/121 DIV CON

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/J.H.A.A./	NAGAI, et al., "Powder Dosage Form of Insulin for Nasal Administration," <i>J. Control Rel.</i> , 1:15-22 (1984).		
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Sheet	13	of	14	Attorney Docket Number	PDT 120/121 DIV CON

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/J.H.A.A./		HEINEMANN, et al. "Current Status of the development of inhaled insulin" <i>Br. J. Diabetes Vasc Dis</i> 4:295-301 (2004).	
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Sheet	14	of	14	Attorney Docket Number	PDT 120/121 DIV CON
RAZ, et al. "Pharmacodynamic and pharmacokinetics of dose ranging effects of oralin versus s.c. regular insulin in Type 1 diabetic patients," <i>Fourth Annual Diabetes Technology Meeting</i> , Philadelphia, PA, 2004. <b>Not provided</b>					

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